Inventors:

PTQ-0038

Van Eyk and Arrell

Serial No.:

09/942,498

Filing Date:

August 30, 2001

Page 3

New claims 16-21 have been added. Support for new claims 16 and 17 is provided in the specification at page 16, lines 19-24, wherein phosphatases and kinase acting on MLC1 phosphorylation are described. Support for new claims 18 and 19 is provided in the specification at page 6, lines 30-34, and page 11, lines 12-14 wherein the human MLC1 and rat MLC1 phosphorylation sites are defined. Support for new claims 20 and 21 is provided in the specification at page 1, lines 17-23, page 12, lines 19-27, and page 14, lines 25-31, wherein conditions and/or factors causing muscle damage are described. Thus, no new matter has been added by this amendment.

Claims 1-15 have been subjected to the following Restriction Requirement:

Group I, claims 1-3, 12 and 14, drawn to a method for identifying muscle protective agents, classified in class 435, subclass 7.4, for example;

Group II, claims 4-6 and 13, drawn to a composition, classified in class 424, subclass 400, for example;

Group III, claims 7-8, drawn to a method for protecting muscle from damage, classified in class 435, subclass 4, for example;

Group IV, claim 9, drawn to a method for altering muscle

PTQ-0038

Inventors:

Van Eyk and Arrell

Serial No.:

09/942,498

Filing Date:

August 30, 2001

Page 4

contractility, classified in class 435, subclass 6, for example; and

Group V, claims 10-11 and 15, drawn to a method for evaluating muscle status, classified in class 435, subclass 7.21, for example.

The Examiner suggests that these Groups are distinct.

Specifically, with respect to Groups II and III, the Examiner has acknowledged their relatedness as product and process of use but suggests that they are distinct because other products may be used to protect cardiac and skeletal muscles from damage.

With respect to the remaining Groups, the Examiner suggests that the claims are directed to different inventions with no connection in design, operation and/or effect.

Applicants respectfully traverse this Restriction Requirement.

At the outset, Applicants respectfully disagree with the Examiner's suggestion with respect to Groups II and III that products other than those of Group II may be used in the method of Group III. Claims of Group III are dependent claims and are limited to a method of protecting cardiac and skeletal muscle from damage comprising contacting the cardiac or skeletal muscle

Inventors:

PTQ-0038

Van Eyk and Arrell

Serial No.:

09/942,498

Filing Date:

August 30, 2001

Page 5

with the composition of Group II. Thus, contrary to the Examiner's suggestion, the claimed method of Group III cannot be conducted with other products used to protect cardiac and skeletal muscles from damage.

Further, Applicants respectfully disagree with the Examiner's suggestion that Groups I:II, I:III, I:IV; I:V, II:IV, II:V, III:IV, III:V and IV:V are not connected in design, operation and/or effect. All of claims of the instant application relate to the discovery that MLC1 phosphorylation is linked with protection and/or damage of cardiac and skeletal muscle. Thus, Applicants respectfully disagree that the Groups set forth by the Examiner are distinct.

Further, MPEP § 803 sets forth two criteria which must be met for a proper restriction requirement. The first is that the inventions be independent or distinct; the second is that there would be serious burden on the Examiner if the restriction is not required. A search for prior art relating to methods for assessing the ability of an agent to increase MLC1 phosphorylation (as set forth in Group I) should also reveal any references teaching compositions with this activity (as set forth in Group II) and use of such compositions (as set forth in Group III), as well as references relating to the effects of MLC1

PTQ-0038

Inventors:

Van Eyk and Arrell

Serial No.:

09/942,498

Filing Date:

August 30, 2001

Page 6

phosphorylation on contractility (as set forth in Group IV) and references relating to methods for monitoring MLC1 phosphorylation to assess skeletal and cardiac muscle disease status (as set forth in Group V). Thus, including all claims in the prosecution of this application should not place any undue or serious burden on the Examiner.

Accordingly, the instant Restriction Requirement meets neither of the criteria as set forth by MPEP §803 to be proper. Reconsideration and withdrawal of this Restriction Requirement is therefore respectfully requested.

Should the Examiner make this Restriction Requirement final, it is respectfully requested that reconsideration be given to inclusion of claim 10 in Group I. Like claims 1-3, 12 and 14, claim 10 is drawn to a method of assessing the phosphorylation status of MLC1 to ascertain protection of the muscle.

Accordingly, Applicants believe that claim 10 is neither independent nor distinct from the claims of Group I and that there is no substantial burden placed upon the Examiner by including claim 10, as well as claims of Group I, in the prosecution of the instant application.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group I, claims 1-3, 12 and 14,

Inventors:

Serial No.: Filing Date:

Page 7

PTQ-0038

Van Eyk and Arrell

09/942,498

August 30, 2001

with traverse.

Respectfully submitted,

Kathleen A. Tyrrell

Registration No. 38,350

Date: <u>July 30, 2002</u>

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515